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09/993,312	11/13/2001	Leroy E. Hood	P - IS 4988	5632

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/993,312	HOOD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Carolyn L Smith	1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2003 and 25 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 44-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 35-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |                                                                                                                     |                                                                             |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                         | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>05302003</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' elections with traverse of Group I (claims 1-43), specie A (a data integration map which is a physical interaction map), specie C (a biochemical system which is a cell), specie F (data elements which are in the form of nucleic acid expression), and specie N (a behavior which is an expression level) as well as amendments, filed 5/30/03 and 9/25/03, are acknowledged. Claims 44-74 are withdrawn from consideration as being drawn to non-elected Groups. Claim 34 is withdrawn from consideration due to being directed to a non-elected species, directed to both a nucleic acid and polypeptide expression data element.

Applicants' traversal is on the grounds that while the claims of Group I are patentably distinct from those of Groups II through VI, a thorough search of Group I claims will identify art relevant to Groups II through VI which would not result in a serious search burden on the Examiner. Applicants further request that Group I be rejoined with at least one of the other Groups.

This is found unpersuasive as each of the groups contain divergent subject matter that would create an undue search burden on the Examiner. Restriction is deemed proper because the Groups contain patentably distinct inventions and the divergent subject matter would create an undue search burden on the Examiner as additional subject matter would need to be searched.

Applicants state the search of Group I involve comparing data integration maps would include a search of methods to prepare a data integration map as found in Group II. This is found unpersuasive as predicting behavior (Group I) and identifying functionally interactive

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components in a biochemical system (Group II) are clearly divergent subject matter. A search of Group I does not automatically contain the subject matter of Group II. An additional search would be necessary if Group II was also examined.

Applicants state the search of Group I involve comparing data integration maps would include a search of methods used to prepare and expand a data integration map as stated in Group III. This is found unpersuasive as predicting a behavior of a biochemical system (Group I) and identifying a component of a biochemical network via physical interaction map refinement (Group III) are clearly divergent subject matter. A search of Group I does not automatically contain the subject matter of Group III. An additional search would be necessary if Group III was also examined.

Applicants state the search of Group I involve comparing data integration maps would include a search of methods used to identify a component of a biochemical network as stated in Group IV. This is found unpersuasive as predicting a behavior of a biochemical system (Group I) and identifying components in a biochemical network via noting changes in a candidate network component due to perturbation (Group IV) are clearly divergent subject matter. A search of Group I does not automatically contain the subject matter of Group IV. An additional search would be necessary if Group IV was also examined.

Applicants state the search of Group I involve comparing data integration maps would include a search of methods used to compare data integration maps of different conditions of a biochemical system as found in Groups V and VI. This is found unpersuasive as comparing maps (Group I), screening compounds that restore a perturbation state of a biochemical system (Group V), and diagnosing/prognosing a pathological condition (Group VI) are clearly divergent

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subject matter. A search of Group I does not automatically contain the subject matter as stated in Groups V and VI. Additional searches would be necessary if Groups V and VI were also examined.

Applicants further traverse the species election which is found unpersuasive for the reasons given below. Applicants are reminded that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. It is appreciated that Applicants selected one specie from each applicable specie election requirement, so that initial examination of the application may proceed.

Applicants state that specie A and B are patentably distinct but a search of both would not pose an undue burden on the Examiner. This is found unpersuasive as different kinds of data integration maps are clearly divergent subject matter. A search of physical interaction map (specie A) does not automatically contain the subject matter of other types of data integration maps (specie B). Additional searches would be necessary if specie B was also examined.

Applicants state a search and examination of more than one species (C, D, or E) would not pose an undue burden on the Examiner. This is found unpersuasive as different kinds of biochemical systems are clearly divergent subject matter with each focusing on a different level. A search of a cell (specie C) does not automatically contain the subject matter of a tissue (specie D) or an organism (specie E). Additional searches would be necessary if species C and D were also examined.

Applicants state this specie election (F, G, H, I, or J) should be reconsidered because the data integration maps generally contain at least two types of data elements. This is found

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unpersuasive as the claims of Group I merely mention, for example, the use of two or more data elements. This is reasonably interpreted to be two data elements, which are not necessarily two *different* data elements. The claims, as written, do not encompass all types and combinations of data elements as the Applicants suggest. A search of a nucleic acid expression data element (specie F) does not automatically contain the subject matter of species G through K. Additional searches would be necessary if species G through K were also examined.

Applicants state a search of species L through O would not pose an undue burden on the Examiner because they would be encompassed by a common search with respect to comparing data integration maps. This is found unpersuasive as the search of Group I and elected species would not encompass all of the subject matter in species L through O. The different kinds of behavior as found in species L through O are clearly divergent subject matter. A search of expression level (specie N) does not automatically contain the subject matter of other types of behaviors as found in species L, M, and O. Additional searches would be necessary if species L, M, and O were also examined.

The restriction is still deemed proper and therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to multiparameter integration methods for the analysis of biological networks, whereas in contrast the elected claims are specifically directed to a method of predicting a behavior of a biochemical system.

The Information Disclosure Statement, filed 5/30/03, has been considered.

Claims herein under examination are 1-33 and 35-43.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-33 and 35-43 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to lack any physical result performed outside of a computer.

As stated in MPEP § 2106, (IV)(2)(b), to be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(2)(b)(i)), or (B) be limited to a practical application within the technological arts (discussed in MPEP § 2106 (IV)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(2)(b)(i), the independent physical acts may be post- or pre-computer processing activity as described below:

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Another statutory process is one that requires the measurements of physical objects or

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activities to be transformed outside of the computer into computer data (In re Gelnovatch, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); Arrhythmia, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. Schrader, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval Arrhythmia, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; Abele, 684 F.2d at 909, 214 USPQ at 688; In re Taner, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(2)(b)(ii), the computer-related process may be limited to a practical application in the technological arts as described below:

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See Arrhythmia, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 1-33 and 35-43 do not fulfill either of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims 1-33 and 35-43 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

As stated in MPEP § 2106, (IV)(B)(1), If the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not



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being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59.

Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a “mathematical algorithm”); or
- simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

Claims 1-33 and 35-43 do not fulfill any of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 and 35-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 1, line 5, recites the phrase “said data integration map” which is rejected due to the lack of clear antecedent basis for this phrase. Claim 1, line 3, mentions “two or more data integration maps”, but it is unclear which of these maps the one map is referred to in the phrase

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“said data integration map”. Clarification of the proper antecedent basis for this phrase is requested. Claims 2-15 are also rejected due to their dependency from claim 1.

Claims 16 (line 9) and 32 (lines 10-11) recite the phrase “said value sets” which is rejected due to the unclarity of this phrase. In claim 16, part (a), “value sets of two...” are contained in the first data integration map. Then, part (b), the second data integration map is stated as containing “said value sets...”. The “said value sets” phrase is reasonably pointing to these value sets in the first data integration map and therefore are not perturbed “value sets” as might be expected in the production of the second data integration map in part (b). Thus, the content of the second and first data integration maps seems to be identical. It is unclear if Applicants wanted to have the value sets in the second, perturbed, data integration map to be different due to the perturbation. This option seems, however, to be precluded by the word “said” in the phrase “said value sets” in part (b) of claim 16. It is also unclear how there can be a change in value sets as identified in part (c) of claim 16 with the value sets being the same between the first and second data integration maps. The same issue is present in claim 32. Clarification of this issue via clearer claim wording is requested. Claims 17-31, 33, and 35-43 are also rejected due to their dependency from claims 16 and 32.

Claims 30 and 43 require the repeating of steps (b) and (c). This is confusing as such repeats will produce multiple second data integration maps. It is unclear what correlation is therefore determinative of the comparison of part (c) with multiple second data integration maps. Clarification of this issue via clearer claim wording is requested.

***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-33 and 35-43 are rejected under 35 U.S.C. 102(a) as being anticipated by Stoughton et al. (P/N 6,351,712).

Stoughton et al. disclose methods for predicting expression levels (behaviors) of cells (biochemical system) in response to a perturbation (abstract). Stoughton et al. disclose comparing microarray profiles (data integration maps that are physical interaction maps) with other profiles (col. 2, line 45). These profiles contain a collection of quantitative measurements (value sets of data elements) of various behaviors, such as the following three value sets: gene expression levels, mRNA abundance, and protein expression levels, that change in response to drug treatments (physical interactions) and other perturbations in the cell (col. 1, lines 14-27 and 38-41) which represent different conditions. The term “network” is broadly defined in several ways in the instant specification (page 10, line 26 to page 11, line 32) which includes a group of interacting molecules in two or more pathways and have common function in a biochemical function. A “network” is also defined as containing one or more components involved in a biochemical function which could be interpreted to be a cell, nucleic acid, or countless other

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cellular component parts. Thus, two cells involved in a microarray as discussed by Stoughton et al. would qualify as two independent networks. Stoughton et al. disclose comparing different pools of nucleic acid on microarrays involving one pool of cell culture exposed to a pathway perturbation and another pool of cell culture not exposed to a pathway perturbation (col. 9, lines 16-36). The pool of nucleic acid exposed to a pathway or drug perturbation represent perturbed conditions for substantially all components within a network (col. 3, lines 28-31), as stated in claims 8 and 23. Stoughton et al. disclose comparing microarrays with control DNA and perturbed DNA (col. 9, lines 40-49) and, alternatively, using DNA from a different perturbed state of the biological system (col. 9, lines 52-54) which illustrates using one or more perturbed conditions in at least three networks. Stoughton et al. disclose a scanned image on a graphics program that is then analyzed using an image gridding program to create a spreadsheet (col. 10, lines 33-41) which further illustrates the data integration map. Stoughton et al. disclose applying perturbations (drugs) at several levels of strength to a biological system to observe responses and interpolating responses (col. 18, lines 5-14). Stoughton et al. disclose using least squares fit (col. 18, line 28) and correlation coefficients between profiles (col. 23, lines 10-18). Stoughton et al. disclose classifying profiles according to their similarity to profiles of known biological significance, such as response patterns for known drugs or perturbations in specific biological pathways (value sets) (col. 23, lines 14-18). Stoughton et al. disclose measuring induced changes in transcript level of at least 2 genes to more than 1000 genes (col. 17, lines 40-45) which is represents at least five components for each network, as stated in claims 14, 29, and 41. Stoughton et al. disclose running repeat experiments (col. 4, lines 33-36) so that the correlative changes discussed above include value sets within the same network, as stated in claims 9 and

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24. The experiments discussed above that contain exposure and non-exposure of drugs contain value set within different networks, as stated in claims 10, 25, and 38. Stoughton et al. disclose genes increasing or decreasing their expression in groups when they possess similar regulatory sequence patterns which results in coordinated response (expression data elements) to particular signaling inputs (col. 18, lines 56-61), as stated in claims 12, 27, and 39. Stoughton et al. disclose genetic redundancy caused by gene duplications and its evolution in networks of transcriptional regulators will tend to co-vary to the extent mutations have not led to functional divergence in regulatory regions (col. 19, lines 1-6).

Thus, Stoughton et al. anticipate the instant invention.

Claims 1-33 and 35-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rine et al. (P/N 5,777,888).

Rine et al. disclose a method for generating and analyzing (comparing) an output signal matrix to an output signal matrix database (containing other matrices) for correlating candidate stimuli and responses (abstract and col. 1, line 66 to col. 2, line 3 and col. 2, lines 25-29). Rine et al. disclose constructing a stimulated physical matrix (data integration map which is a physical interaction map) and detecting a physical signal (value) at each unit of the physical matrix and storing the data with X and Y coordinates of the corresponding physical matrix unit and stimulus, and repeating this procedure to form a database (col. 2, lines 4-15). Rine et al. disclose performing comparisons to generate correlates and qualitative and/or quantitative deduction analyses (col. 5, lines 56-63). Rine et al. disclose using this procedure in testing drug

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administration (perturbation and physical interaction) to identify compounds with a particular biological effect (col. 1, lines 40-57). Rine et al. disclose using an array containing a different responder of a living thing in each unit which may be genes, gene regulatory elements, gene transcripts or translates, or a predetermined functional class or subset of the organism's entire repertoire (col. 2, lines 30-44) which represent at least three networks. Rine et al. disclose deducing the action of a stimulus on the living thing's responders (col. 2, lines 42-44). Rine et al. disclose steps to generate various response profiles (including value sets) for known and unknown stimuli (col. 2, lines 60-64). Rine et al. disclose using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent two or more perturbed conditions. Rine et al. disclose using a wide variety of stimuli and adjusting incubation conditions to preclude cellular stress (col. 3, lines 59-63). Rine et al. disclose measuring gene expression levels in cells (behavior data elements) (col. 4, lines 11-17). Rine et al. disclose measuring cells of the matrix before and after interactions with a pharmacological agent which might include monitoring as a function of other variables such as stimulus intensity, duration, or time (col. 4, lines 51-57), which represents repeated measurements on at least three value sets (as stated in claims 11, 26, and 38) with perturbed conditions for substantially all components within at least one network. Rine et al. disclose performing comparisons to deduce the mechanism of action and characteristics of the responsible stimulus (col. 5, lines 37-49) which represents a prediction of cell behavior (expression level of a biochemical system), as stated in claims 1, 16, and 32. Rine et al. disclose similarities in a shared response pathway in sterol biosynthesis between human cells and yeast cells resulting increased expression levels but in different nucleic acids when exposed to drug

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Mevacor (col. 6, lines 14-28). Rine et al. disclose using a microtiter plate to test an inhibitor on various strains of yeast which various in no expression, increased expression, or decreased expression depending on the strains (col. 6, lines 44-54) which represents inversely coordinated changes in nucleic acid expression data elements, as stated in claims 12, 27, and 39. The term “network” is broadly defined in several ways in the instant specification (page 10, line 26 to page 11, line 32) which includes a group of interacting molecules in two or more pathways and have common function in a biochemical function. A “network” is also defined as containing one or more components involved in a biochemical function which could be interpreted to be a cell, nucleic acid, or countless other cellular component parts. Thus, two cells involved in a microarray as discussed by Rine et al. would qualify as two independent networks. Rine et al. disclose using a microtiter plate with 96 wells with a cell or colony of cells in each well (col. 10, lines 38-41) which represent at least 96 networks. Values taken during the drug interaction measurements over time as discussed above in a 96-well microtiter plate represent value sets within the same network (measurements in the same well) as well as within different networks (measurements in different wells) as stated in claims 9, 10, 24, 25, and 38.

Thus, Rine et al. anticipate the instant invention.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

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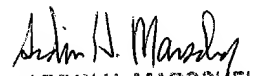
in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 4, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER